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R&D Inc. and Norton (Waterford) Ltd.

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

TEVA BRANDED PHARMACEUTICAL	:	Consolidated Civ. Action No.
	:	20-10172 (JXN) (MAH)
PRODUCTS R&D, INC., and	:	
NORTON (WATERFORD) LTD.,	:	
	:	
Plaintiffs,	:	HIGHLY CONFIDENTIAL –
	:	FILED UNDER SEAL
v.	:	
	:	
CIPLA LTD.,	:	
	:	
Defendant.	:	
	:	

**CORRECTED PLAINTIFFS TEVA PHARMACEUTICAL
PRODUCTS R&D, INC. AND NORTON (WATERFORD)
LTD.'S PROPOSED POST-TRIAL FINDINGS OF FACT
ADDRESSING INFRINGE-MENT, OBJECTIVE INDICIA,
AND ADMISSIBILITY**

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I. Proposed Findings of Fact Regarding Infringement¹

A. Teva Has All Rights, Title, and Interest in the Asserted Patents.

1. Teva holds all rights, title, and interest in each of the Asserted Patents. *See* D.E. 210, at 9 (Undisputed Fact No. 1); D.E. 206-7, 210-7 (List of Facts for Judicial Notice); Tr. 425:10-426:11 (Oral Motion to Admit Stipulated Facts).

B. Cipla Infringes the '289 Patent.

1. Cipla Infringes Claim 1 of the '289 Patent.

2. Cipla's ANDA Product satisfies every limitation of claim 1 of the '289 Patent. *See* Tr. 189:20-190:5-7 (Lewis); PTX-411 (Cipla ANDA Product Sample); PTX-372; PTX-373 (Design Drawings).

3. Claim 1 recites:

1. An inhaler for metered dose inhalation, the inhaler comprising:

a main body having a canister housing,

a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and

a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,

wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and

wherein the canister housing has a longitudinal axis

¹ To the extent that any of the following issues are deemed issues of law, Teva incorporates such issues into its Proposed Conclusions of Law.

X which passes through the center of the central outlet port,

the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X.

JTX-003 ('289 Patent).

a. Cipla's ANDA Product Satisfies the Undisputed Limitations.

4. Cipla does not dispute that its ANDA Products meet any limitation of claim 1 of the '289 Patent except that Cipla disputes whether the rib that lies in a common plane with the actuation member and the central outlet port is an "inner wall canister support formation." *See* Tr. 503:23-504:4 (Anderson).

1) "Inhaler for Metered Dose Inhalation"

5. Cipla's ANDA Product is an "inhaler for metered dose inhalation." *See* Tr. 191:15-20, 192:6-21 (Lewis); PTX-411 (Cipla ANDA Product Sample); D.E. 210, at 9 (Undisputed Fact No. 3); Tr. 425:10-426:11 (Oral Motion to Admit Stipulated Facts); PTX-093 (CIPLA-BDI_0155972, at -974 (Proposed Labeling) ("Inhalation Aerosol: Beclomethasone dipropionate HFA, inhalation aerosol is a pressurized, metered-dose aerosol with a dose counter intended for oral inhalation . . .")); PTX-373 (CIPLA-BDI_0803837-38 (Design Drawing)); *see* PDX-2-033.

6. Cipla's expert did not dispute that Cipla's ANDA Product satisfies this limitation. *See* Tr. 503:22-504:4 (Anderson).

2) "A Main Body Having a Canister Housing"

7. Cipla's ANDA Product comprises "a main body having a canister housing." *See* Tr. 192:23-193:16 (Lewis); PTX-411 (Cipla ANDA Product Sample); PTX-372; PTX-373 (Design Drawings); D.E. 210, at 9 (Undisputed Fact No. 4); Tr. 425:10-426:11 (Oral Motion to Admit Stipulated Facts); PTX-2-034.

8. The parties have agreed that the term "canister housing" should be construed to mean "the portion of the inhaler body that is arranged to retain a medication canister." D.E. 102, at 3.

9. Cipla's ANDA Product comprises a "main body" (*i.e.*, what Cipla refers to as an "actuator"). *See* Tr. 193:5-7 (Lewis). Cipla's main body has a portion which is arranged to retain a medicament canister and is a canister housing. Tr. 193:8-10 (Lewis); PTX-411 (Cipla ANDA Product Sample); PTX-373 (CIPLA-BDI_0803837 (Design Drawings)).

10. At his deposition, Cipla's corporate representative confirmed that Cipla's ANDA Product satisfies this limitation. *See, e.g.*, D.E. 235-1, at 47:5-7 (Rote).

11. Cipla's expert did not dispute that Cipla's ANDA Product satisfies this limitation. *See* Tr. 503:22-504:4 (Anderson).

**3) "A Medicament Canister, Which Is Moveable
Relative to the Canister Housing"**

12. Cipla's ANDA Product comprises "a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing." *See* Tr. 193:17-194:20 (Lewis); D.E. 210, at 9 (Stipulated Fact Nos. 5-6); Tr. 425:10-426:11 (Oral Motion to Admit Stipulated Facts); PTX-411 (Cipla ANDA Product Sample); PTX-093 (CIPLA-BDI_0155972, at -974 (Proposed Labeling)); PTX-373 (CIPLA-BDI_0803837 (Design Drawings)); *see* PDX-2-035.

13. [REDACTED]

14. Cipla's expert did not dispute that Cipla's ANDA Product satisfies this limitation. *See* Tr. 503:22-504:4 (Anderson).

**4) "And Retained in a Central Outlet Port of the
Canister Housing Arranged to Mate with a Can-
ister Fire Stem of the Medicament Canister"**

15. Cipla's ANDA Product comprises "a medicament canister, which is . . . retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister." Tr. 194:22-195:21 (Lewis); D.E. 210, at 9 (Stipulated Fact No. 7); Tr. 425:10-426:11 (Oral Motion to Admit Stipulated Facts); PTX-411 (Cipla ANDA Product Sample); *see* PDX-2-036.

16. Cipla's expert did not dispute that Cipla's ANDA Product satisfies this limitation. *See* Tr. 503:22-504:4 (Anderson).

5) “A Dose Counter”

17. Cipla’s ANDA Product comprises “a dose counter.” Tr. 195:23-197:3 (Lewis); D.E. 210, at 10 (Stipulated Fact No. 8); Tr. 425:10-426:11 (Oral Motion to Admit Stipulated Facts); PTX-372 (Design Drawings); PTX-411 (Cipla ANDA Product Sample); *see* PDX-2-037.

18. Cipla’s expert did not dispute that Cipla’s ANDA Product satisfies this limitation. *See* Tr. 503:22-504:4 (Anderson).

6) “Having an Actuation Member Having at Least a Portion Thereof Located in the Canister Housing for Operation by Movement of the Medicament Canister”

19. Cipla’s ANDA Product comprises “a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister.” Tr. 197:5-204:6 (Lewis); PTX-180 (video showing counting caused by single actuation member); PTX-181 (video with cutout depicting actuation member in inhaler body); PTX-372; PTX-411; *see* PDX-2-038; PDX-2-049; PDX-2-050.

20. Under the Court’s construction, the term “actuation member” means “a component of the dose counter’s actuator that transmits motion from the canister to the actuator.” D.E. 217, at 4; D.E. 218 at 1; Tr. 199:24-200:8 (Lewis).

21. Each of the castellations in Cipla’s ANDA Product is an actuation member. Tr. 197:7-204:6 (Lewis); PTX-180 (video showing counting caused by single actuation member); PTX-181 (video with cutout depicting actuation member in inhaler body); PTX-372 (Design Drawings); PTX-411 (Cipla ANDA Product Sample); *see* PDX-2-038; PDX-2-049; [REDACTED]

22. Each of the castellations in Cipla’s ANDA Product has at least a portion thereof located in the canister housing for operation by movement of the medicament canister. Tr. 198:24-199:4, 199:19-21 (Lewis), PTX-180 (video showing counting caused by single actuation member); PTX-181 (video with cutout depicting actuation member in inhaler body); PTX-372 (Design Drawings); PTX-411 (Cipla ANDA Product Sample); *see* PDX-2-038; PDX-2-049; PDX-2-050.

23. When a patient presses down on Cipla's medicament canister, the medicament canister presses down on the castellations of the actuator, thereby transmitting motion from the medicament canister to the actuator. *See* Tr. 199:19-204:6 (Lewis); PTX-180 (video showing counting caused by single actuation member); PTX-181 (video with cutout depicting actuation member in inhaler body); PTX-411 (Cipla ANDA Product Sample); PTX-093 (CIPLA-BDI_0155972, at -974, 996-98 (Proposed Labeling)); PTX-373 (CIPLA-BDI_0803837 (Design Drawings)).

24. [REDACTED]

25. Cipla's expert did not dispute that Cipla's ANDA Product satisfies this limitation. *See* Tr. 480:1-17; 503:22-504:4 (Anderson).

7) "Wherein the Canister Housing Has an Inner Wall"

26. Cipla's ANDA Product is an inhaler "wherein the canister housing has an inner wall." *See* Tr. 204:7-205:1 (Lewis); D.E. 210, at 10 (Undisputed Fact No. 9); Tr. 425:10-426:11 (Oral Motion to Admit Stipulated Facts); PTX-411 (Cipla ANDA Product Sample); PDX-2-039.

27. Cipla's expert did not dispute that Cipla's ANDA Product satisfies this limitation. *See* Tr. 503:22-504:4 (Anderson).

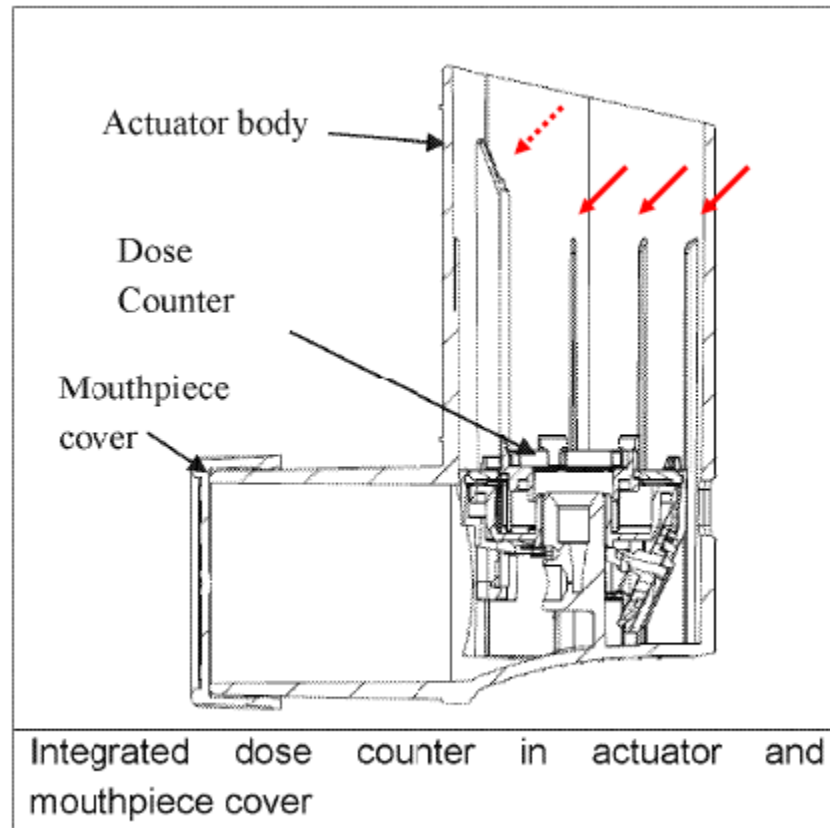
8) "And a First Inner Wall Canister Support Formation Extending Inwardly From a Main Surface of the Inner Wall"

28. Cipla's ANDA Product is an inhaler "wherein the canister housing has . . . a first inner wall canister support formation extending inwardly from a main surface of the inner wall." *See* Tr. 205:4-207:4 (Lewis); PTX-411 (Cipla ANDA Product Sample); PTX-373; *see* PDX-2-040.

29. The parties agreed that the term "inner wall" should be construed to mean "an internal wall of the inhaler body, which includes a main surface of the inner wall and the inner wall through which a portion of the actuation member extends, but excludes the bottom surface, or floor, of the inhaler body," D.E. 102, at 5; the term "canister support formation" should be construed to mean "a formation arranged to reduce canister rocking," D.E. 102, at 4; and the term "main surface of the inner wall" should be construed to mean "inside surface of the vertical cylindrical portion of the

inhaler body, where vertical means substantially parallel to the primary direction of the movement of the medicament canister when it is pressed downward by the user to expel medicament,” D.E. 102, at 5.

30. Cipla’s canister housing has a series of seven “ribs” (three shown by solid red arrows) which extend inwardly from the main surface of the inner wall.² See Tr. 205:4-207:4 (Lewis); PTX-411 (Cipla ANDA Product Sample).



PTX-373 (CIPLA-BDI_0803837 (Design Drawings)); PTX-411 (Cipla ANDA Product Sample).

31. The ribs in Cipla’s ANDA Product are inner wall canister support formations extending inwardly from a main surface of the inner wall. See, e.g., PTX-373

² Cipla referred to the two large protrusions in the front corners of its inhaler (one shown with dotted red line) as “mounting tabs” rather than “ribs.” For purposes of assessing infringement, it is not necessary to determine whether these “mounting tabs” are also “canister support formations.”

(CIPLA-BDI_0803837 (Design Drawings)); PTX-411 (Cipla ANDA Product Sample); Tr. 205:4-207:4, 223:12-22-226:6 (Lewis); *see* PDX-2-040.

32. [REDACTED]

33. [REDACTED]

34. Removal of the ribs results in increased canister rocking, demonstrating that the ribs are “arranged to reduce canister rocking.” *See* Tr. 223:12-226:6 (Lewis).

35. Cipla’s expert did not dispute that at least one of the ribs in Cipla’s ANDA Product is an inner wall canister support formation and therefore that Cipla’s ANDA Product satisfies this limitation. *See* Tr. 479:22-480:9; 503:22-504:4 (Anderson).

9) “Wherein the Canister Housing Has a Longitudinal Axis X Which Passes Through the Center of the Central Outlet Port”

36. Cipla’s canister housing “has a longitudinal axis X which passes through the center of the central outlet port.” Tr. 207:5-208:5 (Lewis); D.E. 210, at 10 (Stipulated Fact No. 11); Tr. 425:10-426:11 (Oral Motion to Admit Stipulated Facts); PTX-373 (CIPLA-BDI_0803837 (Design Drawings)); PTX-411 (Cipla ANDA Product Sample); *see* PDX-2-041.

37. [REDACTED]

38. Cipla’s expert did not dispute that Cipla’s ANDA Product satisfies this limitation. Tr. 503:22-504:4 (Anderson).

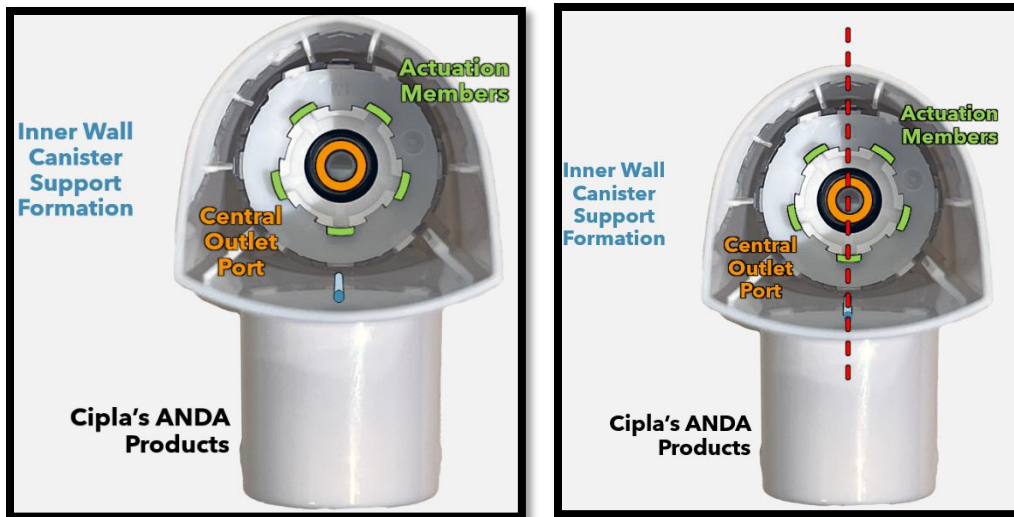
10) “The Inner Wall Canister Support Formation, the Actuation Member, and the Central Outlet Port Lying in a Common Plane Coincident With

the Longitudinal Axis X”

39. Cipla’s ANDA Product satisfies the limitation that requires: “the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X.” Tr. 208:5-212:11, (Lewis); PTX-411 (Cipla ANDA Product Sample); D.E. 206, at 10 (Stipulated Fact No. 11); *see* PDX-2-026; PDX-2-042.

40. Under the Court’s construction, the term “[lying or lie] in a common plane coincident with the longitudinal axis X” means “aligned in a single plane such that a straight line can be drawn through the center of the central outlet port, the canister support formation, and the actuation member.” D.E. 217, at 6; D.E. 218 at 2.

41. A straight line can be drawn through the center of the central outlet port (orange, below), the “front” rib (blue), and an actuation member (green) in Cipla’s ANDA Product, as depicted below in PDX-2-026 (pre- and post-animation).



Tr. 208:5-210:1 (Lewis); PTX-411 (Cipla ANDA Product Sample); PTX-372 (CIPLA-BDI_0156579); PTX-373 (CIPLA-BDI_0803837 (Design Drawings)).

42. Cipla’s expert did not dispute that a straight line can be drawn through the center of the central outlet port (orange, above), the “front” rib (blue), and an actuation member (green) in Ciplas’ ANDA Product, as depicted above in PTX-2-026 (pre- and post-animation). *See* Tr. 503:22-504:4 (Anderson). Cipla’s expert disputed only that the “front” rib shown in blue above is an inner wall canister support formation. *See* Tr. 503:22-504:4 (Anderson).

43. If the front rib in Cipla's ANDA Product is an inner wall canister support formation, then Cipla's ANDA Product infringes the '289 Patent. *See* Tr. 503:22-504:4 (Anderson).

b. The "Front" Rib Is an Inner Wall Canister Support Formation.

44. The parties agreed that the term "inner wall" should be construed to mean "an internal wall of the inhaler body, which includes a main surface of the inner wall and the inner wall through which a portion of the actuation member extends, but excludes the bottom surface, or floor, of the inhaler body." D.E. 102, at 5.

45. The parties agreed that the term "canister support formation" should be construed to mean "a formation arranged to reduce canister rocking," D.E. 102, at 4.

1) The Front Rib is Visibly Arranged to Reduce Canister Rocking.

46. One can "tell by simply looking" that the front rib is a "formation arranged to reduce canister rocking." Tr. 213:12-16 (Lewis).

47. The front rib visibly extends inwardly into the inhaler body, and "by extending into the cavity of the inhaler body . . . [it] necessarily limits the canister's freedom of movement in the direction of the front of the device." Tr. 206:20-207:4, 370:25-371:8 (Lewis).

48. When the canister is pushed toward the front rib, it touches the rib before it touches the inner wall of the inhaler, and thus the front rib is visibly "arranged to reduce canister rocking." *See, e.g.*, Tr. 213:11-16, 217:23-218:4; 218:14-219:5, 221:25-222:8, 400:11-22; 375:24-376:7 (Lewis).

49. No more is needed to appreciate that the front rib in question is "arranged to reduce canister rocking." Tr. 222:9-12.

2) Dr. Lewis's Experiments Confirm that the Front Rib is Arranged to Reduce Rocking.

50. Dr. Lewis performed multiple experiments in support of his opinion that the front rib is arranged to reduce canister rocking. *Infra* ¶¶ 51-72. Mr. Anderson offered no experimental data or videos of his own to contradict Dr. Lewis's work. Tr. 519:8-521:6 (Anderson).

a) Cipla's Canister Rocks More in the Absence of Ribs.

51. Dr. Lewis compared the amount of canister rocking that can occur in Cipla's device "as supplied"—i.e., with all ribs and mounting tabs present—with a version of Cipla's device in which he removed all the ribs (but not the mounting tabs). Tr. 223:12-224:1. In the absence of the ribs, Cipla's canister can rock more than it can when the ribs are present. *Id.* at 224:2-226:6. Removal of the ribs results in more than a millimeter of additional front to back" rocking (*i.e.*, rocking towards or away from the front rib).

52. More than one millimeter of additional rocking is an amount that is "highly significant" in the context of dose counter accuracy. Tr. 224:17-225:4 (Lewis).

53. Removal of the front rib is responsible for at least some of the increase in canister rocking possible when all ribs are removed. Tr. at 226:7-25, 378:12-379:8 (Lewis).

b) Removal of the Front Rib Causes Canister Rocking that Causes Dose Counter Errors.

54. In PTX-178, Dr. Lewis recorded an experiment in which he altered a sample of Cipla's ANDA Product to remove all the ribs but leave the mounting tabs in place. PTX-178; Tr. 229:13-25, 231:12-14, 247:24-25, 248:6-10. He then rocked the canister in the direction of the (now-absent) front rib, Tr. 230:1-13, and depressed the canister, Tr. 248:11-2. The canister then slid down the front wall of the inhaler in the location where the rib *would* have been located had it not been removed. *See* Tr. 248:16-21, 249:25-250:2, 372:11-373:2, 385:20-386:8, 403:17-404:7, 404:19-21 (Lewis); PTX-178 (Video).

55. In this experiment, when the canister is rocked forward, only the effect of the front rib is measured—the fact that other ribs in the back of the inhaler have also been removed is irrelevant. *See* Tr. 230:7-12; 247:24-248:4 (Lewis); PTX-178 (Video).

56. This experiment demonstrates that the front rib is arranged to reduce canister rocking, since in the rib's absence, the canister can contact the inhaler wall at the rib's former location. *See* Tr. 248:16-21, 249:25-250:2, 372:11-373:2, 403:17-404:7, 404:19-21 (Lewis). In contrast, if the rib were present, "it will touch it, it will restrict movement." Tr. 385:20-386:8.

57. In the same experiment, when the canister is rocked in the direction of the missing front rib, and is then depressed such that it slides down the wall where the rib would have been, Cipla's dose counter can experience a "count-not-fire" error whereby the dose counter increments even though medication is not dispensed. *See* Tr. 229:23-231:21, 246:17-247:12, 247:24-250:23 (Lewis); PTX-178 (Video).

58. PTX-178 depicts eight "count-not-fire" errors. PTX-178; Tr. 248:22-249:4; *see also* Tr. 268:12-269:15 (explaining errors observable when counting happens but no dose is audible).

59. The agreed-upon construction of "canister support formation" does not require reduction or prevention of count-not-fire errors. D.E. 102, at 4-5.

60. Nevertheless, the fact that when the front rib is removed, the canister can rock so far towards the front of the inhaler that count-not-fire errors occur is evidence that the front rib is "arranged to reduce rocking." Tr. 385:20-386:16; *see also* 229:5-231:21, 246:17-247:12, 247:24-250:23; 268:12-269:15; 384:22-385:3.

61. Dr. Lewis's experiment in PTX-178 demonstrates that the front rib is arranged to reduce canister rocking because in the rib's absence the canister can rock sufficiently to cause an unwanted count. *See* Tr. 229:5-231:21, 246:17-247:12, 247:24-250:23; 384:22-385:3; 385:20-386:16; *see also* 268:12-269:15 (Lewis).

62. Teva's invention (an inner wall canister support formation in a common plane with the actuation member and central outlet port) was designed to reduce precisely this kind of rocking, and exactly these kinds of dose counter inaccuracies. Tr. 169:16-171:13 172:9-173:2.

63. Cipla did not offer any evidence to rebut Dr. Lewis's experiments. Mr. Anderson did not present them or the devices used in them, because Dr. Anderson destroyed those devices before trial. Tr. 520:21-521:8.

64. The rocking shown in PTX-178 and narrated by Dr. Lewis is "rocking" within the meaning of the parties' agreed-upon construction for "canister support formation." D.E. 102, at 4; Tr. 405:14-406:10.

65. Nothing in the parties' agreed upon construction limits the timing at which rocking may occur. Tr. 405:14-406:10. Patients rock the canister while depressing it, before depressing it, and after depressing it, Tr. 272:19-24; 357:17-359:25; 404:22-405:1, and each of these actions is "rocking" within the meaning of the parties' agreed-upon construction. Tr. 405:14-406:10.

66. Regardless of whether Cipla's device is biased to overcount, rocking leads to dose counter errors when the front rib of Cipla's device is removed. PTX-178; Tr. 229:5-231:21, 246:17-247:12, 247:24-250:23.

67. "Priming" an inhaler means firing the inhaler into the air, rather than into a patient's mouth. PTX-093 at 2.

68. Cipla offered no experiments to show that if two "priming" shots had been recorded in PTX-178, the result of Dr. Lewis's experiments would have been different. Tr. 519:8-521:6 (Anderson).

69. The "twist" performed by Dr. Lewis in PTX-178 properly mates the inhaler into the body, 248:11-14 (the only purpose Mr. Anderson identified for priming, Tr. 495:12-496:13).

70. Dose counters must be designed *not* to miscount given typical patient use—*i.e.*, use that does not comply with the patient leaflet, such as failure to follow priming instructions. Tr. 494:11-495:11

71. In PTX-178, Dr. Lewis's experiment recorded eight "fire-not-count" errors, and it is undisputed that the dose counter should not have counted those compressions regardless of whether it had been primed. PTX-178; Tr. 391:22-392:12; 405:10-13.

72. The unwanted dose counter actuation shown in PTX-178 are the consequence of removing the front rib and reflect the errors Teva's invention was designed to prevent. Tr. 169:16-171:13 172:9-173:2; 384:22-385:3; 385:20-386:16.

3) Cipla Adduced No Relevant Evidence of Non-Infringement.

73. Cipla's expert, Mr. Anderson, did not offer his own opinion that the front rib in Cipla's device is not "arranged to reduce canister rocking." Tr. 479:14-21.

74. Instead, Mr. Anderson testified only that he was not able to determine whether Dr. Lewis had demonstrated that the front rib in Cipla's device "does anything to prevent rocking." Tr. 479:14-21. The substance of Mr. Anderson's opinion consists of a single word ("No") without analysis. *Id.*

75. Mr. Anderson's testimony does not apply the proper claim construction. The parties agreed-upon construction for "canister support formation" was "a

formation arranged to *reduce* canister rocking,” not one (per Mr. Anderson’s testimony) to “*prevent*” rocking.³ D.E. 102, at 4.

76. It is undisputed that there is “very much” a difference between *reducing* rocking and *preventing* rocking. Tr. 407:1-22.

77. To infringe claim 1, the front rib need only be arranged to “reduce” canister rocking. Tr. 407:1-22.

78. Mr. Anderson’s testimony did not address whether the front rib is arranged to reduce canister rocking, and Dr. Lewis’s testimony is therefore unrebutted. Tr. 479:14-21.

4) Cipla Adduced No Credible Testimony of Non-Infringement.

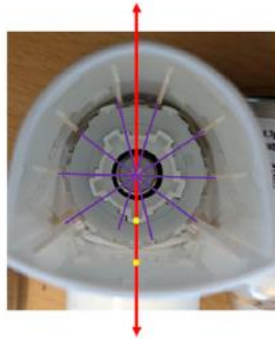
79. Mr. Anderson’s conclusory opinion that the front rib is not an “inner wall canister support formation” is not credible because it contradicts his prior sworn testimony at deposition, where he agreed four times that the front rib is an “inner wall canister support formation.” Tr. 513:22-514:14 (discussing “transcript snap number 6” (D.E. 248 at 87:12-14)); Tr. 508:18-509:19 (discussing “Transcript Snap No. 4” (D.E. 248 at 137:18-23)); Tr. 510:7-511:2 (playing “Video Clip A” (D.E. 248 at 137:24-138:2)); Tr. 511:12-13 (playing “Video Clip B” (D.E. 248 at 138:3-8)).

80. At deposition, Mr. Anderson testified that there is a small inner wall canister support formation in between the two mounting tabs (*i.e.*, at the location of the front rib). Tr. 513:22-514:14 (discussing “transcript snap number 6,” D.E. 248 at 87:12-14 (“Q. In between the two mounting tabs is a small inner wall canister support formation, right?” A. Yes.”)).

81. In the context of the image below, from DDX2.34, Mr. Anderson testified at deposition that the front rib (“marked with a yellow dot”) is an inner wall canister support formation that lies in the common plane. Tr. 508:18-509:19 (discussing “Transcript Snap No. 4,” D.E. 248 at 137:18-23 (“Q. Sorry, you agree that there are seven inner wall canister support formations in defendants’ ANDA products that do not lie in a common plane with the center of the central outlet port and castellation

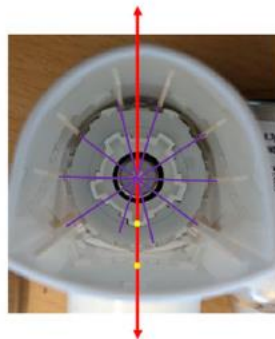
³ Cipla sought to introduce equally conclusory testimony under the correct construction, Tr. 469:10-13, but the Court properly precluded this testimony given Mr. Anderson’s failure to apply that construction in his report, Tr. 469:14-479:12.

[actuation member], right? A. Well wait a minute. 'There is one that is in the common plane, yes, that has been marked with a yellow dot.'"))).



82. At deposition, Mr. Anderson testified that there is an inner wall canister support formation between the two mounting tabs (*i.e.*, at the location of the front rib). 'Tr. 510:7-511:2 (playing "Video Clip A", D.E. 248 at 137:24-138:2 ("Q. . . . There is one inner wall canister support formation, that is the one between the two mounting tabs, right? A. Yes."))).

83. In the context of the image below, from DDX2.34, Mr. Anderson agreed at deposition that "the inner wall canister support formation in between the two mounting tabs of defendants' ANDA product does lie in a common plane with a castellation [*i.e.*, actuation member] and the center of the central outlet port as shown by the red line." *See* Tr. 511:12-13 (playing "Video Clip B", D.E. 248 at 138:3-8).



5) Mr. Anderson's Narrative Regarding the Purpose of the Front Rib Does Not Preclude the Rib from Being an Inner Wall Canister Support Formation.

84. The term "dose counter connecting rib" is not used in the field of metered dose inhalers and was coined by Cipla for purposes of trial. 'Tr. 516:17-518:16

(Anderson); 256:6-11 (Lewis). The name given to the front rib is not relevant to whether the rib is “arranged to reduce canister rocking.” Tr. 256:12-14 (Lewis).

85. A rib that “provides an interference fit” between the dose counter and the inhaler body may also be “arranged to reduce canister rocking”—Mr. Anderson did not testify to the contrary, Tr. 482:15-484:11, and several of the ribs Cipla *concedes* are inner wall canister support formations also provide such interference fits. Tr. 408:5-15.

86. [REDACTED]

6) No Evidence Supports Cipla’s Attorney Argument that the Mounting Tabs Prevent the Front Rib from Being Arranged to Reduce Canister Rocking.

87. Cipla offered no testimony, experiments, or data in support of its attorney argument that the mounting tabs prevent the canister from rocking and contacting the front rib. Tr. 479:14-21, 482:15-484:11, 519:8-521:8 (Anderson).

88. The undisputed evidence shows that the mounting tabs “did not interfere with Dr. Lewis’s testing,” Tr. 223:19-224:1; 229:13-25, and “are deliberately put out of the way of inhalation, the mouthpiece, as well as the canister and the airways,” Tr. 366:10-367:4 (Lewis).

89. Dr. Lewis testified that when the canister is placed in the inhaler body and is rocked, it hits the front rib and not the mounting tabs. Tr. 374:22-375:5

2. Cipla Infringes Claim 2 of the ’289 Patent.

90. Claim 2 of the ’289 Patent recites: “The inhaler as claimed in claim 1 wherein the medicament canister is movable relative to the dose counter.” JTX-003 (’289 Patent).

91. Cipla’s ANDA Product satisfies all limitations of claim 1. Tr. 257:22-258:6 (Lewis); *supra* Section I.B.1.

92. Moreover, Cipla’s ANDA Product satisfies the limitation requiring “wherein the medicament canister is movable relative to the dose counter.” *See*

256:24-260:17, PTX-411 (Cipla ANDA Product Sample); D.E. 210, at 9 (Undisputed Fact No. 12); Tr. 425:10-426:11 (Oral Motion to Admit Stipulated Facts); PTX-372;

93. Cipla's expert did not dispute that Cipla's ANDA Product satisfies comprises a "medicament canister movable relative to the dose counter." *See* Tr. 522:19-523:8 (Anderson).

3. Cipla Infringes Claim 4 of the '289 Patent.

94. Claim 4 of the '289 patent recites: "The inhaler as claimed in claim 1, wherein the first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body." JTX-003 ('289 Patent).

95. Cipla's ANDA Product satisfies all limitations of claim 1. *See* Tr. 257:22-258:6 (Lewis); *supra* Section I.B.1.

96. Cipla's ANDA Product further satisfies the limitation requiring that "the first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body." Tr. 260:18-261:5 (Dr. Lewis); PTX-372 (Design Drawings); PTX-411 (Cipla ANDA Product Sample); *see* PDX-2-073.

97. [REDACTED]

98. Cipla's expert did not dispute that Cipla's ANDA Product comprises a "first inner wall canister support formation compris[ing] a support rail which extends longitudinally along an inside surface of the main body." *See* Tr. 524:25-525:22 (Anderson).

4. Cipla Infringes Claim 6 of the '289 Patent.

99. Claim 6 of the '289 Patent recites: "The inhaler as claimed in claim 4 further comprising a plurality of support rails each of which extends longitudinally along an inside surface of the main body." JTX-003 ('289 Patent).

100. Cipla's ANDA Product satisfies the limitations of claim 4. Tr. 261:6-11; *supra* Section I.B.3.

101. Cipla's canister housing further has a plurality of inner wall canister support formations (which Cipla refers to as "ribs"), which comprise support rails which extend longitudinally along an inside surface of the main body. *See* Tr. 261:6-262:7 (Lewis); PTX-411 (Cipla ANDA Product Sample); D.E. 210, at 10 (Undisputed Fact No. 10); Tr. 425:10-426:11 (Oral Motion to Admit Stipulated Facts).

5. Cipla Infringes Claim 7 of the '289 Patent.

102. Claim 7 of the '289 Patent recites: "The inhaler as claimed in claim 6, wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main body to face each other." JTX-003 ('289 Patent).

103. Cipla's ANDA Product satisfies the limitations of claim 6. Tr. 262:5-15 (Lewis); *supra* Section I.B.4.

104. Under the Court's construction, the term "positioned at opposite ends of the inside surface of the main body to face each other" means "positioned at opposite ends of the inside surface of the main body to face each other." D.E. 217, at 9.

105. Cipla's ANDA Product further satisfies the limitation that "two of the plurality of support rails are positioned at opposite ends of the inside surface of the main body to face each other." *See* Tr. 262:8-24 (Lewis); PTX-411 (Cipla ANDA Product Sample); PTX-372 (Design Drawings); *see* PDX-2-075.

C. Cipla Infringes the '587 Patent.

1. Cipla Infringes Claim 1 of the '587 Patent.

a. Claim 1 of the '587 Contains One Additional Limitation Beyond Claim 1 of the '289 Patent.

106. Claim 1 of the '587 Patent recites:

1. An inhaler for metered dose inhalation, the inhaler comprising:

a main body having a canister housing,

a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and

a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,

wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall,

wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, and

wherein the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with the longitudinal axis X such that the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.

JTX-004.

107. Claim 1 of the '587 Patent and claim 1 of the '289 Patent are substantively identical, except for the yellow language shown in PDX-2-078. The grey language is the same between both claims, the green language is the common plane limitation, and the yellow language reflects the additional limitation regarding "unwanted actuation of the dose counter." *See* Tr. 263:6-264:2 (Lewis).

'289 Patent, Claim 1	'587 Patent, Claim 1
<p>1. An inhaler for metered dose inhalation, the inhaler comprising: a main body having a canister housing, a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister, wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X.</p>	<p>1. An inhaler for metered dose inhalation, the inhaler comprising: a main body having a canister housing, a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister, wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, and wherein the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with the longitudinal axis X such that the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.</p>

108. By virtue of establishing infringement of claim 1 of the '289 Patent, Teva has demonstrated that Cipla's ANDA Products meet all the grey and green language of claim 1 of the '289 Patent—in order to prove infringement of the claim 1 of the '587 Patent, Teva need only further show that Cipla's device meets the requirement that the “first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.” *See id.* 266:14-21 (Lewis).

b. In Cipla's ANDA Products, the Front Rib “Protects Against Unwanted Actuation of the Dose Counter by Reducing Rocking of the Medicament Canister Relative to the Main Body of the Inhaler.”

109. In Cipla's ANDA Products, the front rib “protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.” JTX-004 ('587 Patent).

110. The parties agreed that “protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler” should be construed to mean “against unwanted actuation by reducing rocking of the medicament canister relative to the main body of the inhaler that would otherwise be of a magnitude sufficient to move the dose counter's actuator enough to cause unwanted incrementing (or decrementing) of the dose counter.” D.I 102 at 5.

111. Removal of all ribs in Cipla's ANDA Product results in increased canister rocking, demonstrating that the ribs are "arranged to reduce canister rocking." *See* Tr. 223:12-22, 224:2-226:6 (Lewis).

112. Removal of the front rib is responsible for at least some of the increase in canister rocking possible when all ribs are removed. Tr. at 226:7-25, 378:12-379:8; (Lewis).

113. When the canister is rocked in the direction of the missing front rib, and is then depressed such that it slides down the wall where the rib would have been, increased canister rocking can lead to a "fire-not-count" error whereby the dose counter increments even though medication is not dispensed. *See* Tr. 229:4-250:23, 267:22-270:19 (Lewis); PTX-178 (Video).

114. In this experiment, when the canister is rocked forward, only the effect of the front rib is measured—the fact that other ribs in the back of the inhaler have also been removed is irrelevant. *See* Tr. 230:7-12; 248:1-4 (Lewis); PTX-178 (Video).

115. This experiment demonstrates that the front rib in Cipla's ANDA Product guards against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler. *See* Tr. 223:12-22, 224:2-226:6, 267:22-270:19 (Lewis).

116. Because Dr. Lewis's experiment in PTX-178 demonstrates that the front rib in Cipla's ANDA Product guards against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler, Cipla infringes claim 1 of the '587 Patent. Tr. 267:22-270:19 (Lewis).

117. PTX-178 and the experiment reflected therein demonstrates that—contrary to Mr. Anderson's math modeling—it *is* possible to rock Cipla's canister enough to create a count. PTX-178; 272:4-14. Mr. Anderson's "math model" (*see* PDX-2-068) incorrectly concludes the opposite because it fails to consider that patients may rock the canister as it is being depressed. Tr. 270:23-273:8. Patients engage in precisely the kind of rocking behavior Mr. Anderson's math model ignores and Dr. Lewis's experiment reflects. Tr. 272:15-273:3; PTX-178.

118. Cipla offered no experiments or data of its own to contradict Dr. Lewis's experimental conclusions based on PTX-178. Tr. 271:2-13 (Lewis); 519:8-521:6 (Anderson).

2. Cipla Infringes Claims 2, 4, 6, and 7 of the '587 Patent.

119. The dependent limitations of claims 2, 4, 6, and 7 of the '587 Patent are substantively identical the dependent limitations of claims 2, 4, 5, and 7 of the '289 Patent. *Compare* JTX-003 ('289 Patent), *with* JTX-004 ('587 Patent); *see* PDX-2-084.

120. Cipla infringes the dependent claims of the '587 Patent for the same reasons it infringes the dependent claims of the '289 Patent. *See* Tr. 283:2-14 (Lewis); *supra* Sections I.B.1 – I.B.5.

a. Cipla Infringes Claim 2 of the '587 Patent.

121. Claim 2 of the '587 Patent recites:

2. The inhaler as claimed in claim 1 wherein the medication canister is movable relative to the dose counter.

JTX-004.

122. Cipla's ANDA Product satisfies all limitations of claim 1 of the '587 Patent. *Supra* Section I.C.1.

123. Cipla's ANDA Product further meets the limitation "wherein the medication canister is moveable relative to the dose counter." *See* 256:24-260:17, PTX-411 (Cipla ANDA Product Sample); D.E. 210, at 9 (Undisputed Fact No. 12); Tr. 425:10-426:11 (Oral Motion to Admit Stipulated Facts); PTX-372.

124. Cipla's expert did not dispute that Cipla's ANDA Product comprises a "medicament canister movable relative to the dose counter." *See* Tr. 522:19-523:8 (Anderson).

125. This limitation is substantially identical to a limitation appearing in claim 2 of the '289 Patent, *compare* JTX-003 ('289 Patent), *with* JTX-004 ('587 Patent); *see* Tr. 283:2-14 (Lewis). Cipla infringes Claim 2 of the '587 Patent on the basis of the same facts that show infringement of claim 2 of the '289 Patent. *Supra* Section I.B.2.

b. Cipla Infringes Claim 4 of the '587 Patent.

126. Claim 4 of the '587 Patent recites:

4. The inhaler as claimed in claim 1, wherein the first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body.

JTX-004.

127. Cipla's ANDA Product satisfies all limitations of claim 1. *Supra* Section I.C.1.

128. Cipla's ANDA product further satisfies the limitation "wherein the first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body." Tr. 260:18-261:5 (Dr. Lewis); PTX-372 (Design Drawings); PTX-411 (Cipla ANDA Product Sample); *see* PDX-2-073.

129. [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED].

130. Cipla's expert did not dispute that Cipla's ANDA Product meets this limitation. *See* Tr. 524:25-525:22 (Anderson).

131. This limitation is substantially identical to a limitation appearing in claim 4 of the '289 Patent, *compare* JTX-003 ('289 Patent), *with* JTX-004 ('587 Patent); *see* Tr. 283:2-14 (Lewis). Cipla infringes Claim 4 of the '587 Patent on the basis of the same facts that show infringement of claim 4 of the '289 Patent. *Supra* Section I.B.3.

c. Cipla Infringes Claim 6 of the '587 Patent.

132. Claim 6 of the '587 Patent recites

6. The inhaler as claimed in claim 4 further comprising a plurality of support rails each of which extends longitudinally along the inside surface of the main body.

JTX-004.

133. Cipla's ANDA Product satisfies the limitations of claim 4. Tr. 261:6-11; *supra* Section I.C.2.b.

134. Cipla's canister housing further has a plurality of inner wall canister support formations (which Cipla refers to as "ribs"), which comprise support rails which extend longitudinally along an inside surface of the main body. *See* Tr. 261:6-262:7 (Lewis); PTX-411 (Cipla ANDA Product Sample); D.E. 210, at 10 (Undisputed Fact No. 10); Tr. 425:10-426:11 (Oral Motion to Admit Stipulated Facts).

135. This limitation is substantially identical to a limitation appearing in claim 4 of the '289 Patent, *compare* JTX-003 ('289 Patent), *with* JTX-004 ('587 Patent); *see* Tr. 283:2-14 (Lewis). Cipla infringes Claim 6 of the '587 Patent on the basis of the same facts that show infringement of claim 6 of the '289 Patent. *Supra* Section I.B.4.

d. Cipla Infringes Claim 7 of the '587 Patent.

136. Claim 7 of the '587 Patent recites:

7. The inhaler as claimed in claim 6, wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main body to face each other.

JTX-004.

137. Cipla's ANDA Product satisfies the limitations of claim 6. Tr. 262:5-15 (Lewis); *supra* Section I.C.2.d.

138. Under the Court's construction, the term "positioned at opposite ends of the inside surface of the main body to face each other" means "positioned at opposite ends of the inside surface of the main body to face each other." D.E. 217, at 9.

139. Cipla's ANDA Product further satisfies the limitation that "two of the plurality of support rails are positioned at opposite ends of the inside surface of the main body to face each other." *See* Tr. 262:8-24 (Lewis); PTX-411 (Cipla ANDA Product Sample); PTX-372 (Design Drawings); *see* PDX-2-075.

140. This limitation is substantially identical to a limitation appearing in claim 4 of the '289 Patent, *compare* JTX-003 ('289 Patent), *with* JTX-004 ('587 Patent); *see* Tr. 283:2-14 (Lewis). Cipla infringes Claim 7 of the '587 Patent on the basis of the same facts that show infringement of claim 7 of the '289 Patent. *Supra* Section I.C.2.d.

3. Cipla Infringes Claim 12 of the '587 Patent.

141. Claim 12 of the '587 Patent is nearly identical to claim 1 of the '587 Patent, except that its final limitation requires "that the first inner wall canister support formation protects against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member." JTX-004 ('587 Patent). Claim 12 recites:

12. An inhaler for metered dose inhalation, the inhaler comprising:

a main body having a canister housing,

a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and

a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,

wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall,

wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, and

wherein the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with the longitudinal axis X such that the first inner wall canister support formation protects against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member.

JTX-004.

142. Thus, if the front rib of Cipla's ANDA Products "protects against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member," Cipla's ANDA Product infringes claim 12 of the '587 Patent. JTX-004 ('587 Patent).

143. The front rib of Cipla's ANDA Product protects against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member. JTX-004 ('587 Patent); Tr. 282:18:283:1 (Lewis).

144. Unlike the requirement in claim 1 of the '587 Patent to protect against only "unwanted actuation" (*i.e.*, "count-not fire errors"), claim 12's reference to "dose count errors" includes *both* "count-not-fire" and "fire-not-count" errors, and limits the direction of rocking to rocking "towards or away from the actuation member." JTX-004 ('587 Patent); Tr. 277:13-278:3 (Lewis).

145. Removal of all ribs in Cipla's ANDA Product results in increased canister rocking, demonstrating that the ribs are "arranged to reduce canister rocking." *See* Tr. 223:12-22, 224:2-226:6 (Lewis). Removal of the front rib is responsible for at least some of the increase in canister rocking possible when all ribs are removed. Tr. at 226:7-25, 378:12-379:8 (Lewis).

146. When the canister is rocked in the direction of the missing front rib, and is then depressed such that it slides down the wall where the rib would have been, Cipla's dose counter can experience a "fire-not-count" error whereby the dose counter increments even though medication is not dispensed. *See* Tr. 229:5-231:21, 246:17-247:12, 247:24-250:23 (Lewis); PTX-178 (Video).

147. In this experiment, when the canister is rocked forward, only the effect of the front rib is measured—the fact that other ribs in the back of the inhaler have also been removed is irrelevant. *See* Tr. 230:7-12, 248:1-4 (Lewis); PTX-178 (Video).

148. This experiment demonstrates that the front rib in Cipla's ANDA Product protects against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member. *See* Tr. 223:12-22, 224:2-226:6 (Lewis).

149. Likewise, in a second experiment, when the canister is rocked in the direction of the missing front rib, and is then depressed such that it slides down the wall where the rib would have been, Cipla's dose counter can experience a "count-not-fire" error whereby medication fires but the dose counter does not increment. *See* PTX-179 (Video); Tr. 279:14-282:12 (Lewis).

150. These experiments demonstrate that the front rib in Cipla's ANDA Products against dose count errors in the manner claim 12 requires. *See* Tr. at 282:18-283:1 (Lewis). Cipla's reliance on math modeling is misplaced, *supra* ¶ 117, and its complaints regarding failure to prime are misplaced, *supra* ¶ 67-71. In particular, PTX-179 showed three consecutive instances in which Cipla's inhaler fired but did not count, so even were the first two instances considered "priming" doses, the video still reflects a third dose counter error caused by rocking, Tr. 405:9-13 (Lewis). Regardless, the dose counter should accurately keep track of priming doses just as well as any other dose, and thus all three instances of fire-not-count errors are problematic. Tr. 391:16-392:12; 405:9-13.

D. Cipla Infringes the '808 Patent.

1. Cipla Infringes Claim 28 of the '808 Patent.

a. Cipla's ANDA Product Satisfies Every Limitation of

Claim 1 of the '808 Patent.

151. Cipla's ANDA Product satisfies every limitation of claim 1 of the '808 Patent. *See* Tr. 283:18-296:25 (Lewis); PTX-411 (Cipla ANDA Product Sample); PTX-372 (Cipla Design Drawing); PTX-181 (Video).

152. Claim 1 recites:

1. A dose counter for an inhaler, the dose counter having a counter display arranged to indicate dosage information, a drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input, wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements.

JTX-002 ('808 Patent).

153. To satisfy the requirements of claim 28 of the '808 Patent, a dose counter must satisfy the requirements of claim 1 and further comprise a "regulator" that "provides a resistance force" of "greater than 0.3 N" "against movement of the counter display."

Independent Claim	Additional Limitation
'808 Patent, Claim 1	1. A dose counter for an inhaler, the dose counter having a counter display arranged to indicate dosage information, a drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input, wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements.
Claim(s)	Additional Limitation
'808 Patent, Claim 27	27. The dose counter as claimed in claim 1 in which the regulator provides a resistance force of greater than 0.1 N against movement of the counter display.
'808 Patent, Claim 28	28. The dose counter as claimed in claim 27 in which the resistance force is greater than 0.3 N.

See JTX-002 ('808 Patent); PDX-2-087.

154. The parties have agreed that the term "regulator" means "a structure of the dose counter that modulates motion of the counter display." D.E. 102, at 4.

155. The parties have agreed that the term “regulate motion of the counter display” means “modulate motion of the counter display.” D.E. 102, at 4.

156. The Court construed the term “first station” to mean “a first region” and the term “second station” to mean “a second region.” D.E. 218, at 3.

1) Cipla’s ANDA Product Satisfies the Undisputed Limitations.

157. Cipla’s ANDA Product comprises a “dose counter for an inhaler.” *See* Tr. 284:3-22 (Lewis), 425:7-426:11 (citing D.E. 210, Undisputed Fact ¶ 15); PTX-411 (Cipla ANDA Product Sample); PTX-372 (Cipla Design Drawing).

158. Cipla’s dose counter has “a counter display arranged to indicate dosage information” (*i.e.*, what Cipla refers to as a “units display ring”). *See* Tr. 284:24-287:5 (Lewis); PTX-411 (Cipla ANDA Product Sample); PTX-372 (Cipla Design Drawing).

159. At all times, Cipla’s units display ring indicates dosage information by displaying the units (or ones) digit for each remaining dose. *See* Tr. 286:13-22 (Lewis); PTX-411 (Cipla ANDA Product Sample); PTX-372 (Cipla Design Drawing).

160. When Cipla’s ANDA Product has fewer than ten doses remaining, Cipla’s units display ring indicates all available dosage information because, at those times, the units digit, by itself, indicates the number of doses. *See* Tr. 286:23-287:5 (Lewis); PTX-411 (Cipla ANDA Product Sample); PTX-372 (Cipla Design Drawing).

161. Cipla’s dose counter has “a drive system arranged to move the counter display incrementally” (*i.e.*, what Cipla refers to as a “lid,” “indexer,” and “units teeth ring”). *See* Tr. 287:6-288:5; PTX-411 (Cipla ANDA Product Sample); PTX-372 (Cipla Design Drawing).

162. Cipla’s drive system is arranged to move “the counter display incrementally in a first direction from a first station to a second station in response to actuation input.” *See* Tr. 288:6-290:2 (Lewis); PTX-411 (Cipla ANDA Product Sample); PTX-372 (Cipla Design Drawing).

163. Cipla’s units display ring moves clockwise from one region to another region when a patient actuates the device. *See* Tr. 287:6-290:2 (Lewis); PTX-411 (Cipla ANDA Product Sample); PTX-372 (Cipla Design Drawing).

164. For example, when Cipla’s ANDA Product has ten doses remaining, Cipla’s units display ring moves counterclockwise such that the number displayed

changes from zero to nine. *See* Tr. 286:23-290:2 (Lewis); PTX-411 (Cipla ANDA Product Sample); PTX-372 (Cipla Design Drawing).

165. Cipla and its expert did not dispute that Cipla's ANDA Product satisfies each of the above limitations. *See* Tr. 426:23-498:10 (Anderson) (not discussing above limitations).

2) Cipla's ANDA Product Comprises a "Regulator," Which "Is Arranged to Act Upon the Counter Display at the First Station to Regulate Motion of the Counter Display to Incremental Movements."

166. Cipla's dose counter provides a "regulator," "which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements" (*i.e.*, what Cipla refers to as a "leaf spring"). *See* Tr. 290:3-296:22; 408:19-410:22 (Lewis); PTX-411 (Cipla ANDA Product Sample); PTX-372 (Cipla Design Drawing); PTX-181 (Video).

167. One challenge in designing a dose counter for a metered dose inhaler is ensuring that the counter display moves only in incremental movements. *See* JTX-002, 2:44-62 ('808 Patent); Tr. 182:8-186:14 (Lewis).

168. To overcome this challenge, the inventors introduced a "regulator," which regulates, or modulates, the motion of the counter display to incremental movements in the claimed inventions. *See* JTX-002, 2:44-62, Figs. 6F, 15, 16, 20 ('808 Patent); Tr. 84:9-90:5 (Walsh), 635:12-637:13 (Karg).

169. In Cipla's ANDA Product, the leaf spring regulates and modulates the motion of the counter display (*i.e.*, the units display ring) at the first station to incremental movements. *See* Tr. 292:16-296:22 (Lewis); PTX-411 (Cipla ANDA Product Sample); PTX-372 (Cipla Design Drawing); PTX-181 (Video).

170. When Cipla's ANDA Product is assembled, the canister sits on top of the indexer, which sits on top of the leaf spring, which "sits in the units display ring." Thus, when a patient pushes down on the canister, the canister pushes down on the indexer, which pushes down on the leaf spring, which pushes down on the units display ring. *See* Tr. 291:5-293:11 (Lewis); PTX-411 (Cipla ANDA Product Sample); PTX-372 (Cipla Design Drawing); PTX-181 (Video).

171. If a patient pushes down on the canister with too little force, the leaf spring ensures that the units display ring does not move so as to record a count.

294:1-295:2 (Lewis); PTX-411 (Cipla ANDA Product Sample); PTX-372 (Cipla Design Drawing); PTX-181 (Video).

172. If the patient pushes down with enough force, the leaf spring ensures that the units display ring does not “allow the dose counter to hover between two doses,” but instead ensures that the units display ring increments completely such that it displays the next digit. Tr. 295:3-12 (Lewis); PTX-411 (Cipla ANDA Product Sample); PTX-372 (Cipla Design Drawing); PTX-181 (Video).

173. Claim 28 of the ’808 Patent and the claims from which it depends (*i.e.*, claims 1 and 27) do not require the dose counter be “tape-based.” Although certain claims literally require the dose counter to comprise tape, claims 1, 27, and 28 do not. *Compare, e.g.*, JTX-002, claims 1, 27, 28 *with id.* claims 2-26 (’808 Patent).

174. Fundamental principles of physics—the “laws of Newton”—dictate that if the leaf spring pushes upwards, it must also push downwards against the leaf spring with an “equal and opposite force.” Tr. 291:18-293:11, 294:19-295:22 (Lewis); PTX-411 (Cipla ANDA Product Sample); PTX-181 (Video).

b. Cipla’s ANDA Product Satisfies Every Limitation of Claim 27 of the ’808 Patent.

175. Cipla’s ANDA Product satisfies every limitation of claim 27 of the ’808 Patent. *See* Tr. 297:4-299:6 (Lewis); PTX-411 (Cipla ANDA Product Sample); PTX-372 (Cipla Design Drawing); PTX-181 (Video).

176. Claim 27 recites:

27. The dose counter as claimed in claim 1 in which the regulator provides a resistance force of greater than 0.1 N against movement of the counter display.

JTX-002 (’808 Patent).

177. Cipla’s infringement of claim 27 is further addressed *infra* Section I.D.1c, in connection with claim 28 of the ’808 Patent.

c. Cipla’s ANDA Product Infringes Claim 28 of the ’808 Patent.

178. Cipla's ANDA Product satisfies every limitation of claim 28 of the '808 Patent. *See* Tr. 297:4-299:6 (Lewis); PTX-411 (Cipla ANDA Product Sample); PTX-372 (Cipla Design Drawing); PTX-181 (Video).

179. Claim 28 recites:

28. The dose counter as claimed in claim 27 in which the resistance force is greater than 0.3 N.

JTX-002 ('808 Patent).

180. Cipla's ANDA Product comprises a dose counter as claimed in claim 1. *See supra* Section I.D.1.a.

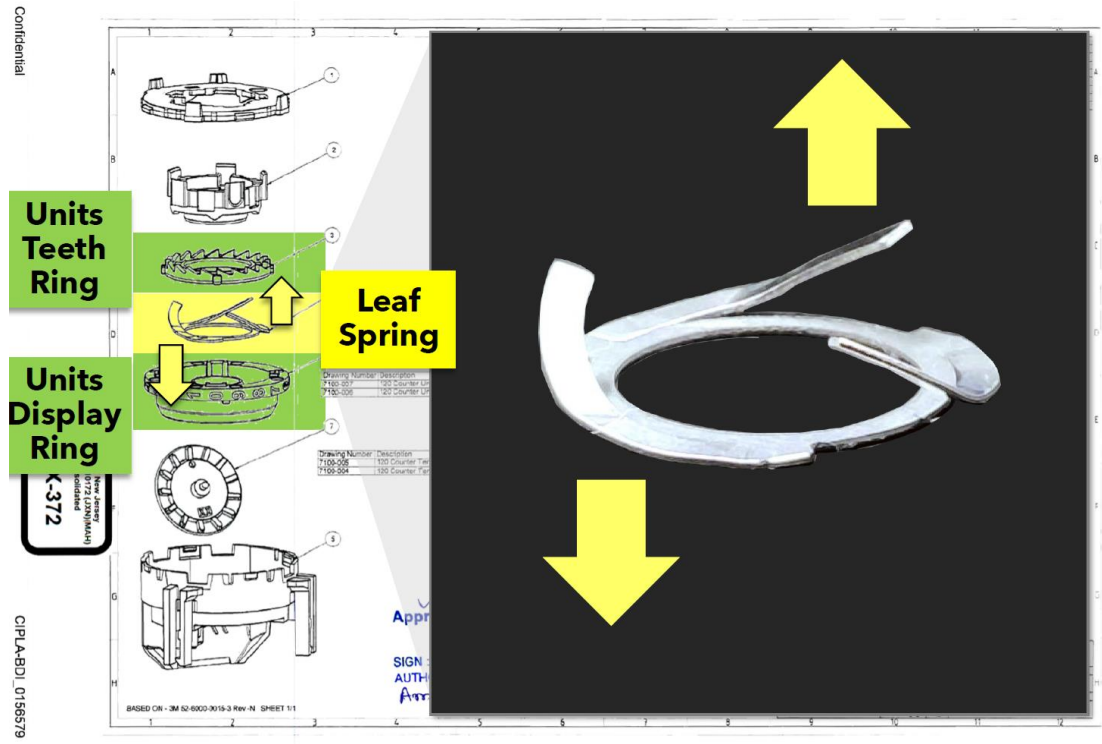
1) Cipla's ANDA Product Comprises a "Regulator" That "Provides a Resistance Force" of "Greater than 0.3 N" "Against Movement of the Counter Display."

181. Cipla's leaf spring "provides a resistance force of greater than 0.1 N against movement of the counter display." *See* Tr. 297:4-299:6, 410:8-22 (Lewis); PTX-411 (Cipla ANDA Product Sample).

182. Cipla's leaf spring provides a "resistance force" that "is greater than 0.3 N" against movement of the counter display. *See* Tr. 297:4-299:6, 410:8-22 (Lewis); PTX-411 (Cipla ANDA Product Sample).

183. Dr. Lewis experimentally measured the force that the leaf spring exerts upwards against the canister at different points in the device's operation and found that the leaf spring exerts a resistance force of greater than 0.3 N against the canister. Those experimental data establish infringement because they show that the leaf spring exerts a resistance force of greater than 0.3 N downwards against the counter display. *See* Tr. 297:4-299:6, 410:8-22 (Lewis); PTX-411 (Cipla ANDA Product Sample).

184. Cipla's canister, indexer, leaf spring, and units display ring all rest on top of one another; thus, measuring the resistance force that the leaf spring exerts upwards against the canister "directly" measures the resistance force that the leaf spring exerts downwards against the counter display because the forces are the same. *See* Tr. 410:13-22 (Lewis); PTX-411 (Cipla ANDA Product Sample).



PDX-2-098 (citing PTX-411 (Cipla ANDA Product Sample); PTX-372 (Cipla Design Drawing)).

185. Mr. Anderson did not conduct any experiments measuring the resistance force exerted by the leaf spring. *See* Tr. 426:23-498:10 (Anderson) (not discussing any experiments).

186. Claim 28 and the claims from which it depends (*i.e.*, claims 1 and 27) do not require the “regulator” to provide a “resistance force” in the opposite direction of the counter display. Rather, the claims require the “regulator” to provide a “resistance force” “against movement of the counter display.” *See* JTX-002, claims 1, 2, 27 (’808 Patent); Tr. 408:19-410:7 (Lewis).

187. Cipla’s leaf spring provides a downwards “resistance force” “against movement” of the units display ring. Tr. 315:2-24, 410:8-22 (Lewis). Whether or not it applies a resistance force in a counterclockwise direction is irrelevant. *See supra* ¶ 186.

188. A “resistance force” need not be in the “opposite” direction of a movement to work “against” it. For example, if a person riding a “child’s roundabout” (or merry-go-round) pushes their “foot down,” “the roundabout will stop. Without [that] foot pushing down and without any friction, the roundabout will continue.” Tr.

315:2-24 (Lewis). Even though the downward force imparted by the rider's foot is not opposite the rotation of the roundabout, it still resists its movement. *Id.* Record players operate by the same principle. Tr. 410:8-22 (Lewis).

189. Mr. Anderson did not offer an opinion that Dr. Lewis's testing was erroneous because Dr. Lewis did not directly measure the counterclockwise force that Cipla's leaf spring imparts on the counter display. Mr. Anderson did not mention the phrases "clockwise" or "counterclockwise" in his rebuttal to Dr. Lewis's infringement testimony. *See* Tr. 426:23-498:10 (Anderson).

II. Proposed Facts Regarding Objective Indicia of Nonobviousness

A. Objective Evidence of Praise Supports the Nonobviousness of the Asserted Claims.

190. ProAir® and Qvar® with dose counter have received extensive praise in the medical industry. *See* Tr. 805:3-811:9 (Panettieri); *infra* ¶¶ 190-197.

191. Dr. Reynold Panettieri has more than thirty of experience in treating pulmonary disorders and has prescribed inhalers (including ProAir® and Qvar®) during that period. *See* 800:12-801:19, 804:7-805:2 (Panettieri).

192. Dr. Panettieri attends "many international conferences" in which he is "able to converse" with his "colleagues who are providers, physicians, physician scientists" and "trade notes on the management of patients." Dr. Panetteri and his colleagues "pretty uniformly" describe ProAir® and Qvar® as "really state of the art" and "best in class inhalers that have dose counters" because of their accuracy, reliability, robustness, and ergonomics. Tr. 805:1-807:17 (Panettieri).

193. Patient use studies report that ProAir® with dose counter "functioned accurately and reliably in the clinical setting" and "significantly reduced" hospitalizations and emergency room visits. Tr. 807:18-811:9 (Panettieri); PTX-121 (Given 2012); PTX-120 (Chipps 2017).

194. Mr. Anderson is not a physician and "is not legally allowed to treat patients"—offered only one criticism of Dr. Panettieri's opinions. Tr. 814:17-816:19; 817:4-818:7 (Anderson).

195. Teva's documents demonstrate that Qvar® and ProAir® with dose counter "meet all asserted claims." Tr. 728:17-729:11 (Lewis); PTX-201 (Qvar® NDA); PTX-212 (ProAir® NDA).

196. The advantages Dr. Panettieri identified results from the claimed and novel features of Teva's inventions. *See* Tr. 76:25-80:12, 84:9-86:18 (Walsh); 633:1-634:17, 635:12-636:24 (Karg); PTX-201, at TEVAQVAR-00008706 (Qvar® NDA); PTX-212, at TEVAQVAR-00052614 (ProAir® NDA); PTX-208 (Teva/Radius Presentation); PTX-231 (Design Drawings).

197. Specifically, the advantages Dr. Panettieri identified result from Qvar®'s and ProAir®'s inclusion of (1) an inner wall canister support formation that lies in a common plane with the actuation member and center of the central outlet port (*i.e.*, the "common plane" limitation of the '289 and '587 Patents) and (2) a "regulator" (*i.e.*, the "regulator" limitation of the '808 Patent). *See* Tr. 76:25-80:12, 84:9-86:18 (Walsh); 633:1-634:17, 635:12-636:24 (Karg); PTX-201, at TEVAQVAR-00008706 (Qvar® NDA); PTX-212, at TEVAQVAR-00052614 (ProAir® NDA); PTX-208 (Teva/Radius Presentation); PTX-231 (Design Drawings).

III. Proposed Findings of Fact Regarding Admissibility

A. Aurobindo's Deposition Testimony Is Relevant.

198. Dr. Jay Holt is Aurobindo's Senior Vice Present of Inhalation Research and Development and is "responsible for choosing actuators [*i.e.*, inhaler bodies] and dose counters to use in Aurobindo's inhalers." D.E. 234-1, at 22:24-23:3, 23:19-24:2 (Holt).

199. Deborah Carr is an Associate Director in Aurobindo's Inhalation Division who worked on Aurobindo's ANDA Product. *See* D.E. 234-1, at 48:17-24, 59:5-7 (Carr).

200. Both Dr. Holt and Ms. Carr have personal knowledge of the research and development of Aurobindo's ANDA Product. D.E. 234-1, at 99:14-101:10; 114:15-115:4, 128:20 (Holt) (describing involvement with various technical and business documents); *id.* at 59:5-7 (Carr); *see also infra* ¶¶ 201-07.

201. [REDACTED]

202. [REDACTED]

203. [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

204. [REDACTED]
[REDACTED]
[REDACTED]

205. [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

206. [REDACTED]
[REDACTED]

a. [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

b. [REDACTED]
[REDACTED]

c. [REDACTED]
[REDACTED]
[REDACTED]

d. [REDACTED]
[REDACTED]
[REDACTED]

e. [REDACTED]
[REDACTED]
[REDACTED]

f. [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

207. [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

208. [REDACTED]

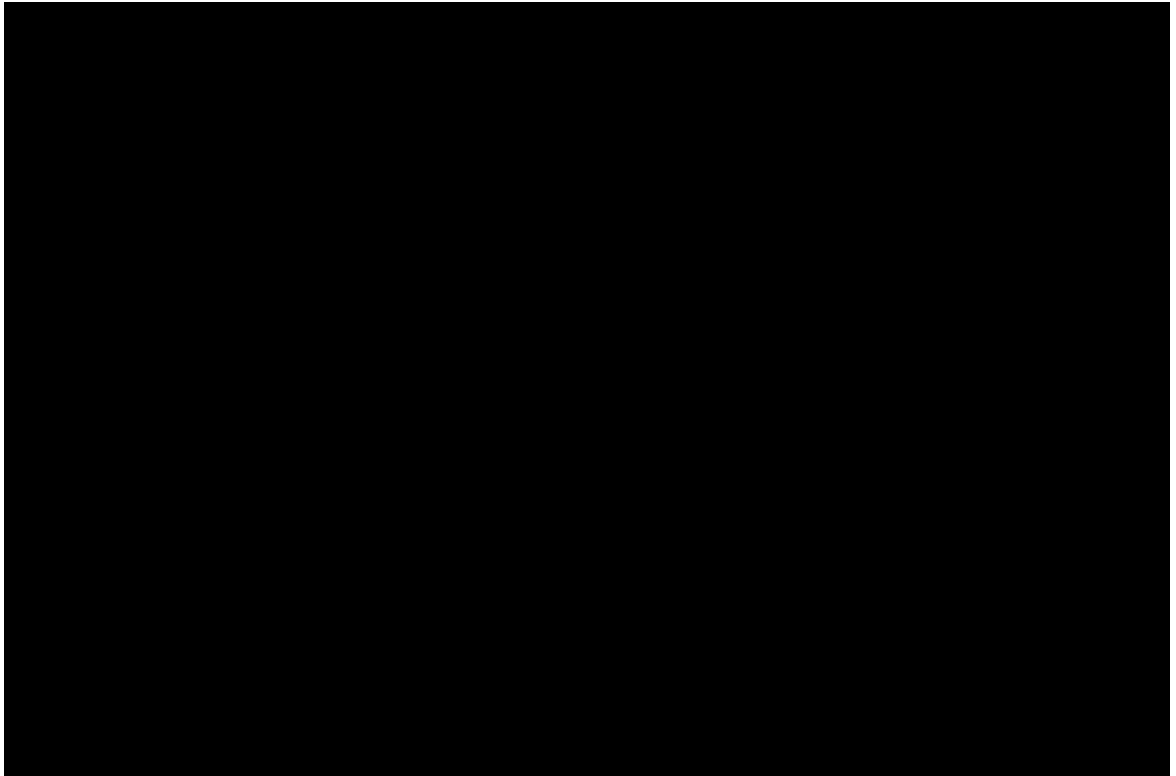
[REDACTED]
[REDACTED]

B. Cipla's and Aurobindo's ANDA Products Are Materially Identical.

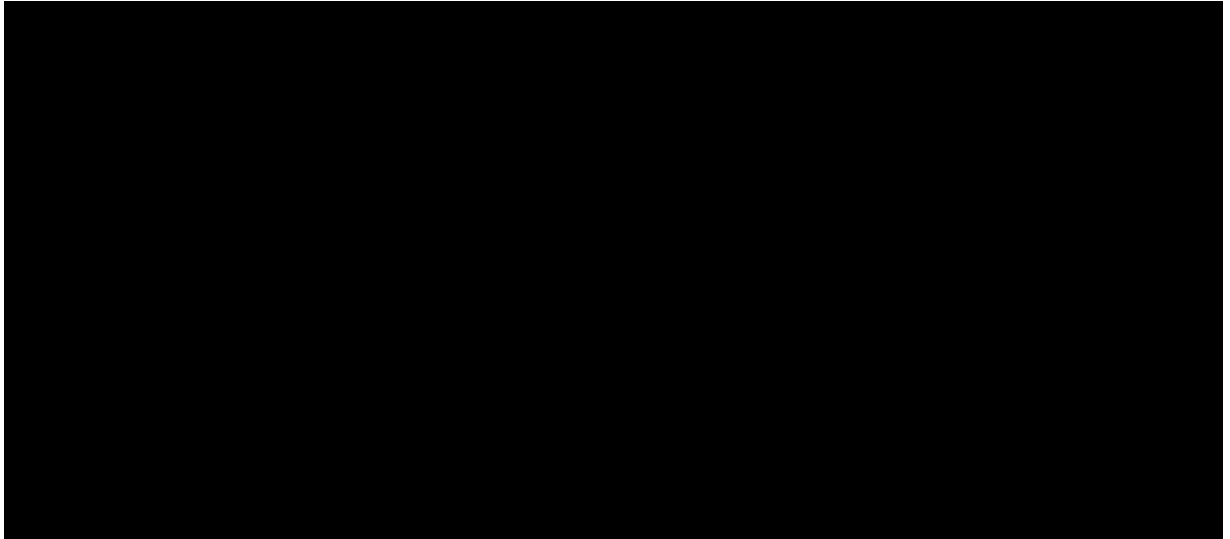
209. Cipla's and Aurobindo's ANDA Products are materially indistinguishable for purposes of infringement. *See* D.E. 235-1, at 24:8-10, 25:2-6, 25:13-27:5, 27:8-28:3, 28:6-10, 28:15-29:14 (Rote, Cipla); PTX-371 at CIPLA-BDI_0010846 (Rote Ex. 2); PTX-372 (Cipla Design Drawing); [REDACTED]

[REDACTED] [REDACTED] [REDACTED]
[REDACTED]

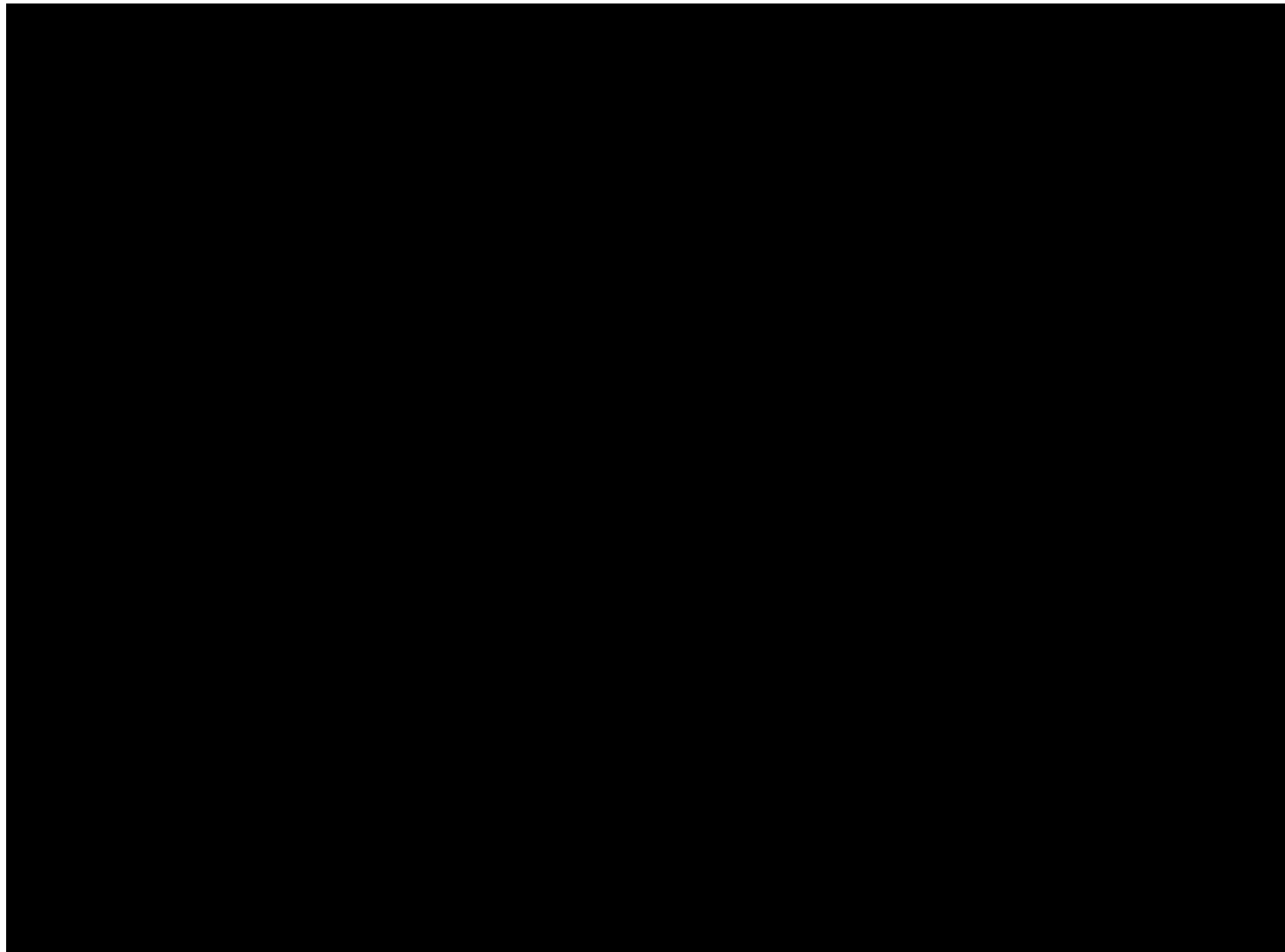
[REDACTED]



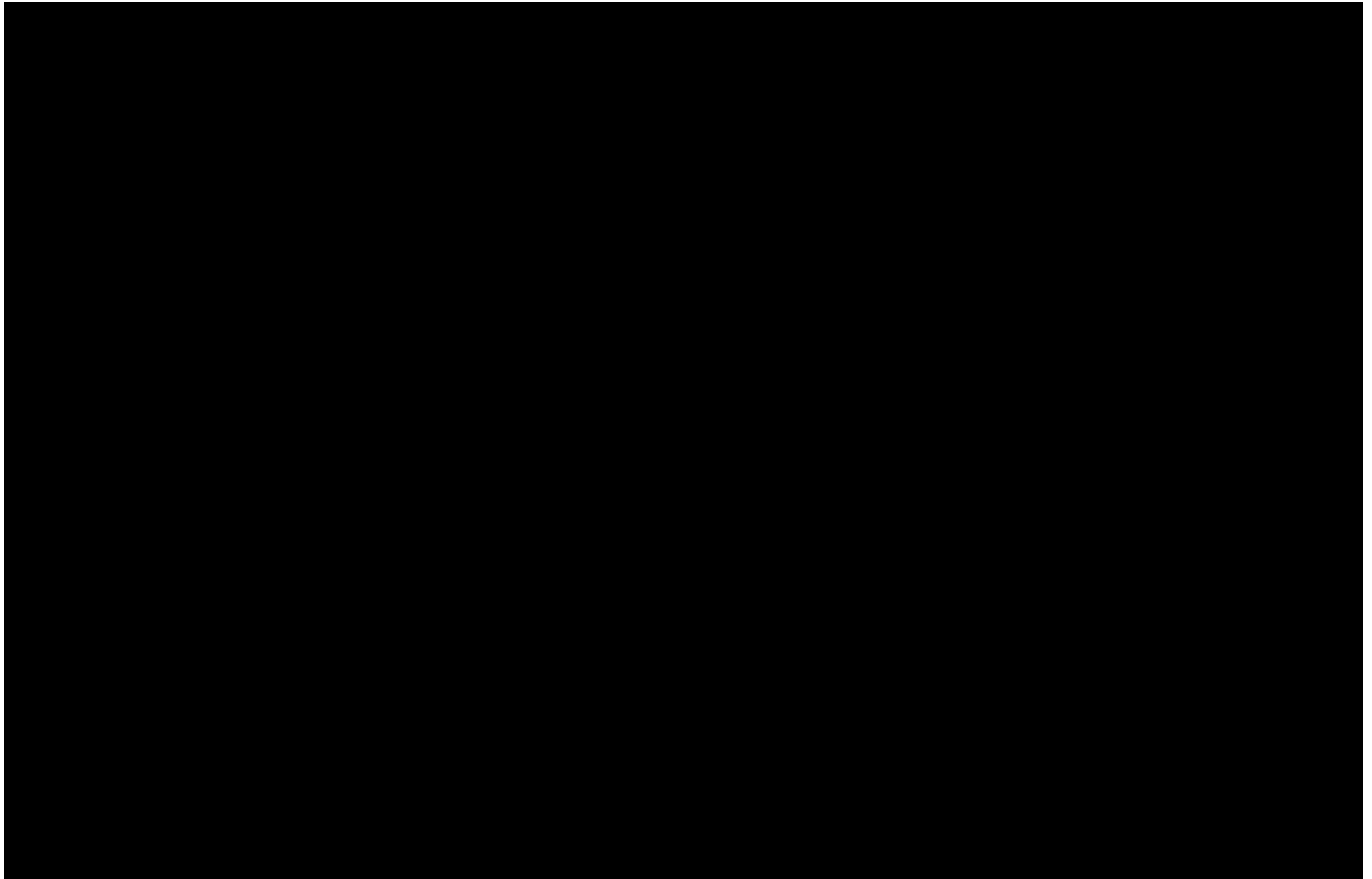
PTX-371 at CIPLA-BDI_0010846 (Rote Ex. 2).



212. Cipla's and Aurobindo's design drawings demonstrate that their
ucts are materially similar for purposes of infringement.



[REDACTED]



PTX-372 (Cipla Design Drawing).

213. Mr. Anderson's Rebuttal Report contains following opinion: [REDACTED]

[REDACTED] As such I concluded that analysis and testing of the Aurobindo ANDA Product or the Cipla ANDA Product would be applicable to the other. I made a visual comparison and took measurements of the Aurobindo ANDA Product and the Cipla ANDA Product to confirm my conclusion." D.E. 157 ¶ 36 (Anderson Reb. Rept.).

214. Dr Lewis testified that there were no "meaningful differences between Cipla's [ANDA Product], whether the product samples or documents, and Aurobindo[s] [ANDA Product]." *See* Tr. 138:9-141:2 (Lewis). Mr. Anderson and Cipla's other witnesses did not contradict Dr. Lewis's testimony on this issue. *See, e.g.,* Tr. 426:23-498:10 (Anderson).

C. Cipla Had Adequate Notice and Opportunity.

215. Cipla had adequate notice of the Aurobindo evidence and opportunity to participate in and respond to the taking of that evidence. *See infra* ¶¶ 216-21.

216. Cipla received the deposition notices for both Dr. Holt and Ms. Carr. Walsh Decl. Exs. H-J.

217. Cipla joined in a joint filing in which Aurobindo stated that it "agrees to designate at least one Rule 30(b)(6) representative and to make available two Rule 30(b)(1) deponents (Jay Holt and Deborah Carr)." D.E. 131, at 1.

218. Cipla had access to the submitted deposition transcripts and documents. *See, e.g.,* Tr. 821:24-822:17 (Anderson).

219. Cipla and Aurobindo were parties to a joint defense agreement. *See* Tr. 416:4-424:2 (Colloquy).

220. Cipla and Aurobindo shared Mr. Anderson as an expert witness. *See, e.g.,* D.E. 157 (Anderson Reb. Rept.).

221. Mr. Anderson conceded that he had access to Aurobindo's witnesses' transcripts (and had, in fact reviewed Ms. Carr's deposition transcript). *See* Tr. 821:24-822:17 (Anderson).

222. At trial, Cipla proffered testimony from its own employee fact witness regarding the functioning of Cipla's ANDA Product. *See, e.g.,* Tr. 538:4-10 (Rote)

(“Q. Can you explain to the Court what an actuator is? A. Yes. So actuator is a plastic device, plastic piece, which is a small aperture of the small orifice at the bottom, and it houses the metallic canister. And when the metallic canister is pressed into this actuator, it produces a soft plume through the orifice, which is then inhaled by a patient to cure the asthma or the COPD.”).

Dated: February 7, 2023

Respectfully submitted,

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